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EXAMINER	
MICHENER, JENNIFER KOLB	
ART UNIT	**PAPER NUMBER**
1762	7

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/894,293	ROORDA, WOUTER	
	Examiner	Art Unit	
	Jennifer Kolb Michener	1762	

-- Th MAILING DATE of this communication app ars on the cov r sh et with the corr spondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,8-18,21,22 and 24-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,8-18,21,22 and 24-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Examiner notes with appreciation Applicant's affirmation of election and cancellation of non-elected claim 7.

Claim Rejections - 35 USC § 112

2. The rejection of claims 21 and 22 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of Applicant's amendment of claim 21 and cancellation of claim 22.

Claim Rejections - 35 USC § 102

3. The rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Jayaraman has been withdrawn in view of Applicant's amendments.

4. The rejection of claims 1, 3-5, 11, and 14 under 35 U.S.C. 102(b) as being anticipated by Fan et al. have been withdrawn in view of Applicant's amendments, in favor of new rejections applied below.

5. The rejection of claims 5, 8, 14-16, and 19-20 under 35 U.S.C. 102(e) as being anticipated by Zhong have been withdrawn in favor of new rejections applied below.

As necessitated by Applicant's amendments, the following new rejection is made:

6. Claims 1, 2 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Tseng et al. (US 6,364,903).

Tseng teaches a method of coating a stent with a coating substance by spraying or dipping the coating substance onto a stent that has been preheated. When the coating substance is applied to the hot stent surface, it fuses directly thereon. The temperature of the stent is inherently maintained at an elevated temperature during application of the coating because Tseng teaches that application is to a hot surface (col. 4).

While claim 1 requires the stent temperature prior to coating to be "greater than ambient", claim 35 merely requires the broad limitation "other than ambient temperature", as present in the originally-filed claims. Nevertheless, by teaching "preheating" Tseng teaches the "other than ambient temperature" limitation of newly-added, broader claim 35.

The stent of Tseng are metal (col. 3, line 45).

Claim Rejections - 35 USC § 103

7. The rejection of claims 12 and 13 under 35 U.S.C. 103(a) as being unpatentable over Fan has been incorporated into the new Fan rejection below.

8. The rejection of claims 6, 9-13, 17-18, and 22-23 under 35 U.S.C. 103(a) as being unpatentable over Zhong has been withdrawn in favor of new rejections applied below.

9. The rejection of claims 22-23 under 35 U.S.C. 103(a) as being unpatentable over Zhong in view of Fan has been withdrawn in favor of new rejections applied below.

10. The rejection of claims 1-4 and 21 under 35 U.S.C. 103(a) as being unpatentable over Zhong in view of Pham et al. has been withdrawn in favor of new rejections applied below.

As necessitated by Applicant's amendment, the following new rejections are applied:

11. Claims 5, 8-14, 22, 26-27, 29, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan et al. (US 5,558,900).

Fan teaches that which was disclosed in the previous office action including application of a coating solution onto a medical device and drying by blowing preheated hot air onto the medical device and placement into a hot oven. The temperature used in Fan is 75 degrees centigrade, which is an increase above ambient temperature.

The fluid/solvent of Fan is inherently evaporated in the drying process of Fan.

Examiner notes that both the blowing of pre-heated hot air and the placement into the oven constitute "directing a gas" as required by Applicant. Since the oven is not said to

be a "vacuum" oven, it will inherently contain some gas which will allow gas to be directed onto the medical device.

The method of Fan is useful in coating "medical devices such as catheters" (abstract) with "hydrophilic", "thromboresistant, lubricious" coatings. Fan states that "an article, e.g., a medical device" is coated (col. 1-2). Additionally, Fan states that his method is "broadly useful for modifying surfaces of various articles, such as, for example, medical devices including but not limited to, catheters, guidewires, medical balloons, contact lenses, implant devices, intrauterine devices, peristaltic pump chambers, endotracheal tubes, gastroenteric feed tubes and arteriovenous shunts" (col. 6). Particularly the lubricious, thromboresistant, hydrophilic coating aids in devices "used for insertion through blood vessels" (col. 1). Therefore, while Fan does not specifically state the word "stent" as an example of a medical device, it is Examiner's position that the broad group of medical devices inserted into blood vessels which would benefit from hydrophilic, lubricious, thromboresistant coatings would be inclusive of stents. It would have been obvious to one of ordinary skill in the art to select "stents" from Fan's class of medical devices used for insertion into blood vessels to be coated by the method of Fan with the expectation of successful results because stents (like catheters, shunts, guidewires, and balloons) require insertion through blood vessels and benefit from thromboresistant, lubricious, hydrophilic coatings.

Regarding the repetition of the coating steps in claim 5 and 26, it is Examiner's position that it would have been obvious to an ordinary artisan to repeat processing steps to achieve a desired thickness of coating, for the reasons outlined in the prior office action.

In general, the transposition of process steps or the splitting of one step into two, where the processes are substantially identical or equivalent in terms of function, manner, and result, was held to not patentably distinguish the processes. *Ex parte Rubin*, 128 USPQ 440 (Bd. Pat. App. 1959.

Regarding claim 8, Examiner notes that application of the coating solution to the device of Fan is by flooding, a form of immersion. While Fan does not specifically teach "spraying", it is Examiner's position that spraying and immersion are obvious variations well-known in the art to provide successful results in achieving uniform coverage to medical devices. It would have been obvious to an ordinary artisan to have substituted spraying for immersion with the expectation of such success.

Regarding claims 9-10, 12-13, and 29, flow rates, durations, and coating volume would have been determined by an ordinary artisan seeking to optimize results for those reasons outlined in the previous office action.
It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claim 11, the temperature of the gas of Fan lies within the range claimed by Applicant.

Regarding claim 14, Fan teaches coating with polymer in fluid as disclosed above.

Fan teaches the limitations of claim 22, as outlined above regarding claim 5 and dependent claims.

Regarding claims 27 and 33, Fan teaches coating and subsequently drying with no "waiting period" disclosed. Therefore it is Examiner's position that it is Fan's intention to dry the medical device as soon as possible after coating with some short delay being inherent and inevitable, such as 0.1-5 seconds. Selection of a delay period that minimizes a waste of processing time would have been within the skill of an ordinary artisan seeking to maximize profits.

Regarding claim 34, Fan teaches ethyl acetate as a solvent (col. 4).

12. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tseng. Tseng teaches that which is disclosed above, including preheating a stent prior to coating, but fails to teach the preheating temperature.
Selection of an optimal temperature for the preheating step would have been obvious to an ordinary artisan based on the type of metal used in the stent substrate, the type of polymer coated onto the stent, and the desired rate of fusing. Determination of optimized variables is within the skill of an ordinary artisan, as outlined above.

13. Claims 8-10, 15-18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan in view of Zhong (US 6,156,373).

Regarding claim 8, Fan teaches flooding or immersing the medical device in the coating solution.

Zhong teaches immersion or spraying to apply a coating solution to a medical device. Since Fan teaches immersion and Zhong teaches immersion or spraying, Zhong would have reasonably suggested interchanging spraying for immersion in the method of Fan with the expectation of achieving similarly uniform, adherent coatings.

Optimization of the variables required by claims 9-10 would have been obvious for those reasons outlined above.

Regarding claims 15-16, Fan teaches that which is disclosed above including applying a heated gas to a coated medical device to evaporate the solvent therefrom. While Fan teaches the desire to create hydrophilic, antithrombogenic, lubricious coatings using polymers in solution, Fan fails to specifically teach addition of therapeutic agents, such as antithrombogenic agents, to the medical device to render the coating antithrombogenic.

Zhong is cited for teaching application of a coating in solution to implantable medical devices useful in blood vessels, for example, but not limited to stents. Zhong teaches application of a polymer in solution with therapeutic agents to the stent, said therapeutic agents being useful as anti-thrombogenic agents, anti-proliferative agents, and

radiochemicals, making the implantable device a drug-delivery system for use in diseased vessels.

Since Fan teaches the desire to create hydrophilic, antithrombogenic, lubricious coatings on medical devices implanted into blood vessels and Zhong teaches the use of therapeutic agents on such devices to accomplish these goals, Zhong would have reasonably suggested the use of therapeutic agents in the solution of Fan. It would have been obvious to use the teachings of Zhong in the method of Fan to render Fan's medical devices "drug delivery systems" for effectively treating diseases of the vessels. Zhong teaches the use of Taxol and radiochemicals as therapeutic agents (col. 7).

Regarding claims 17 and 18, Fan teaches blowing hot air through a catheter in examples 71-73. Fan fails to teach rotating a device or moving it linearly during the application of the hot air. However, the catheter example is merely exemplary. Based on the type of device being treated with hot air, it would have been obvious to an ordinary artisan to be certain to apply the hot air to all surfaces of the device evenly. Such uniform distribution of air would inherently require relative movement between the hot air and the device to be treated.

Zhong teaches application of a coating solution followed by treatment with a gas stream. Zhong teaches movement of the tool used to impinge the gas onto the stents. Figure 5 shows that the tool may be rotated or moved along the linear direction of the longitudinal axis of the stent. While claims 17 and 18 require that the stent be rotated or moved linearly, it is Examiner's position that moving the stent relative to the gas tool is

interchangeable with moving the gas tool relative to the stent. All movement is relative. While Zhong's gas stream is not heated and its primary goal is to remove unwanted solution, Examiner notes that Zhong is cited merely for teaching means to access all areas of a medical device with a gas stream.

Therefore, since Fan teaches directing a stream of heated gas onto a medical device to induce evaporation of solvent from said device and Zhong teaches means to move a tool used to discharge gas onto a medical device, Zhong would have reasonably suggested movement of the gas stream of Fan to access all areas of the medical device. It would have been obvious to an ordinary artisan to use the teachings of Zhong in the method of Fan to provide Fan with a means to access all areas of various medical devices for uniform evaporation of solvent.

It appears that the stent is at least partially expanded, as required by claim 20.

14. Claim 21, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan in view of Tseng et al.

Fan teaches treatment of a medical device with hot air after application of a coating, but fails to teach pre-treatment of the medical device by heating and maintenance of such elevated temperature during application of the coating.

Tseng teaches that which is disclosed above regarding pre-heating a medical device for application of a polymer coating thereto. The medical device is still hot during application of such a coating. Additionally, Tseng teaches that further heating may be

used after coating depending on the type of polymer used. The polymer of Tseng may be applied in fluid form.

Since Fan teaches post-treatment of a medical device with hot air and Tseng teaches that pre-heating the device used in combination with post-heating enables a fused coating on the device, Tseng reasonably suggests the use of pre-heating a medical device in the method of Fan. It would have been obvious to an ordinary artisan to have used the teachings of Tseng in the method of Fan to provide Fan with an increasingly adherent coating.

Regarding claim 30, Fan teaches dimethylformamide as a solvent.

Regarding claim 31, Fan teaches hot air with a temperature lying within range of Applicant.

15. Claims 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan in view of Whitbourne.

Fan teaches application of a polymer solution to a medical device containing, preferably, an isocyanate. Fan fails to teach the use of poly n-butyl methacrylate as the polymer coating.

Whitbourne teaches coating catheters and stents with a solution of polymer such as isocyanates or poly butyl methacrylate (abstract; claim 8).

Since Fan teaches isocyanate polymer coatings on implantable blood vessel prostheses and Whitbourne teaches that such prostheses may be coated with isocyanate or poly butyl methacrylate, Whitbourne would have suggested the use of poly butyl methacrylate in the method of Fan. It would have been obvious to an ordinary artisan to use the interchangeability teachings of Whitbourne in the method of Fan to provide Fan with an alternative polymer for safe use within the body.

Examiner notes that poly butyl methacrylate is inclusive of the "normal" n-butyl-methacrylate required by Applicant.

16. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tseng in view of Whitbourne.

Tseng teaches the use of PTFE or acrylate-based polymers for coating stents (col. 2), but fails to teach the use of poly n-butyl methacrylate as the polymer coating.

Whitbourne teaches coating catheters and stents with a solution of polymer such as acrylates or poly butyl methacrylate (abstract; claim 8).

Since Tseng teaches acrylate coatings on stents and Whitbourne teaches that stents may be coated with acrylates or poly butyl methacrylate, Whitbourne would have suggested the use of poly butyl methacrylate in the method of Tseng for those reasons outlined in the Fan in view of Whitbourne rejection, above.

17. Claims 1, 2, 4, 24, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg (US 5,464,650) in view of Pursley (US 6,030,371).

Berg teaches a method of coating stents by spraying a solution of polymer and therapeutic agent thereon and allowing the solvent to evaporate. What Berg fails to teach is pre-heating the substrate to aid in said evaporation.

Pursley is cited for teaching application of a polymer solution to a pre-heated metal mandrel substrate (abstract; col. 3, lines 32-38; claims 3 and 33). The polymer consolidates as it impacts the pre-heated substrate by driving off the solvent.

Since Berg teaches coating metal stents with a polymer solution with the desire to remove solvent and Pursley teaches a means to remove solvent from polymer-coated metal substrates by preheating the substrate, Pursley would have reasonably suggested preheating the stent of Berg. It would have been obvious to one of ordinary skill in the art to use the teachings of Pursley in the method of Berg as a suitable means of driving off the solvent of Berg's polymer solution.

Regarding claim 24, selection of a temperature would have been optimized by an ordinary artisan as outlined in the above rejections.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer Kolb Michener
January 10, 2003

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